



The National Science Advisory Board for Biosecurity (NSABB): Enhancing Oversight of Dual Use Research

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NSABB:

Status and Purpose

- **The NSABB is a federal advisory committee**
- **NSABB will provide recommendations to the U.S. government**
- **Those recommendations will be directed toward oversight of life sciences research that has been described as “dual use”**



The Issue: “Dual Use” Research

- **Dual use research includes life sciences research:**
 - **with legitimate scientific purpose**
 - **that may be misused to pose a biologic threat to public health and/or national security**



Life Sciences: New Considerations

- **“Dual use” potential of certain life sciences research requires consideration of new processes and procedures designed to minimize the likelihood that biological research will be misused to threaten public health and/or national security.**



Life Sciences: Striking a Balance

- **Goal is to enhance protections for life sciences research while ensuring that any impact to the free flow of scientific inquiry is minimized.**



Evolution of the Oversight of rDNA Technology: A Model for Dual Use Research?

- **1970's:** Advent of recombinant DNA (rDNA) technology stimulates concerns among both scientific community and general public regarding:
 - Safety
 - Environmental impact
 - Potential ethical and social implications



History of Federal Oversight of rDNA Technology

- **Multiple legislative controls were proposed.**
- **Scientific community voluntarily adopted a moratorium on rDNA research**
 - **Until an appropriate framework for oversight was established**



History of Federal Oversight of rDNA Technology

- **1974:** Oversight Framework established
 - Pre-empted pending legislation for regulating all laboratory work with rDNA molecules
 - Consisted of three components:
 - Federal
 - Local
 - “culture of accountability” among researchers



Oversight of rDNA Research: Federal Level

- **1974:** National Academy of Sciences recommended the National Institutes of Health (NIH) as locus for Federal oversight of rDNA research
- **1975:** NIH Recombinant DNA Advisory Committee (RAC) established
 - Advise government on principles and procedures for safe and ethical conduct of rDNA research



Oversight of rDNA Research: Local Level

1976: NIH publishes the *NIH Guidelines on Research Involving rDNA Molecules*

- Widely accepted by research community
- Compliance with procedures and principles is a condition for receipt of federal funds for rDNA research
- Voluntary compliance by private sector
- Federally funded research institutions also required to establish local oversight bodies to oversee day-to-day conduct of rDNA research



Oversight of rDNA Research Today

- **Oversight system established in mid-1970's still in place today**
 - Policies and procedures have evolved with the science
 - Developed in transparent manner with input from scientific community and the public
 - Fosters scientific accountability along with scientific progress
- **Offers potential model for oversight of dual use research**

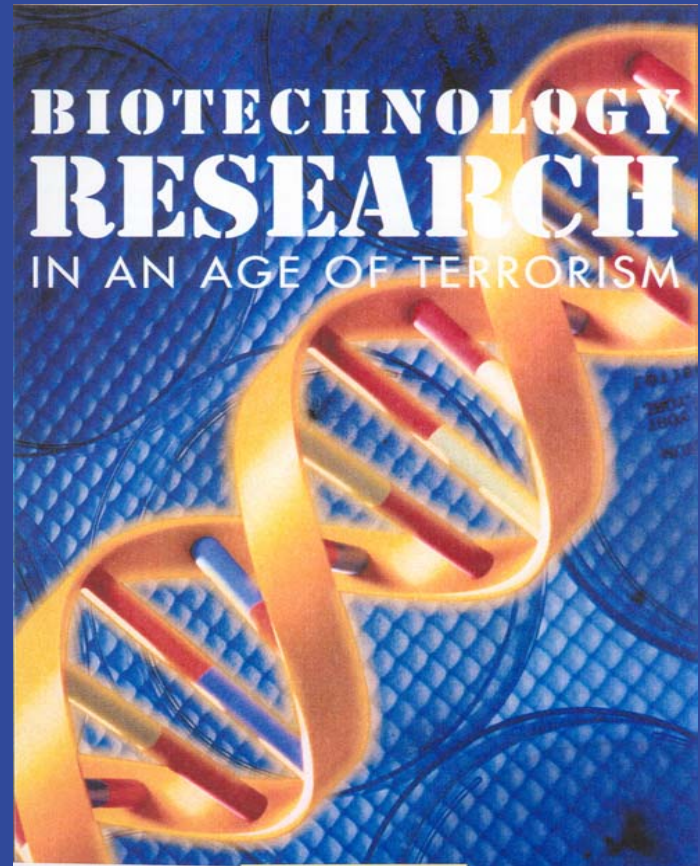


NRC Report on Dual Use Research

Report of the National
Research Council of the
National Academies:

***“Biotechnology
Research in an Age of
Terrorism”***

**[“The Fink Report”]
(October 2003)**





NSABB Charge

- **Advise United States departments and agencies that conduct or support life sciences research**
- **Advise/recommend strategies for oversight of federally supported dual-use research**
- **Not intended to review specific experiments, except as specified in its charter.**



NSABB Charge

Recommend:

- **Criteria for identifying dual use research**
- **Guidelines for oversight of dual use research**
- **Strategies for oversight of new classes of experiments and technologies**



NSABB Charge

Advise on:

- **Program for biosecurity education and training for scientists and laboratory workers in life sciences**
- **A code of conduct for scientists and laboratory workers**
- **National guidelines on communication and dissemination of dual use research methodologies and results**
- **Strategies for coordinated international policies regarding dual use research**



Forming a Federal Advisory Committee: Critical Considerations

- **Design committee framework (i.e., purpose, structure, operations) to adequately address issues of concern**
 - **Define committee scope and authority**
 - e.g. NSABB provides advice to a broad range of US government agencies and departments (18)
 - **Ensure that activities of committee are transparent and provide opportunity for public awareness and input**



Forming a Federal Advisory Committee: Critical Considerations

- **Membership selection must take into account:**
 - **Appropriate expertise**
 - **Broad geographic representation**
 - **Population diversity**
- **Candidates must be screened for conflict of interest**
- **In addition, NSABB candidates must undergo security clearance**



NSABB

Structure and Operations

- **25 voting members appointed by Secretary, HHS, after consultation with other Federal Agencies**
- **Meets quarterly and as needed**
- **Meetings open to public, unless otherwise determined by the Secretary, HHS**
- **Will be managed and administered by Office of Biotechnology Activities, NIH**



Examples of NSABB Member Expertise

- **Microbiology**
- **Clinical ID/diagnostics**
- **Lab biosafety/security**
- **Public health/epidemiology**
- **Health physics**
- **Pharmaceutical production**
- **Veterinary medicine**
- **Plant health**
- **Molecular biology/genomics**
- **Bioethics**
- **National security**
- **Biodefense**
- **Institutional Biosafety Committees**
- **Export controls**
- **Law, law enforcement**
- **Scientific publishing**



NSABB

Department and Agency

Ex Officio Members

- **Exec. Office of the President**
- **Department of Health and Human Services**
- **Department of Energy**
- **Department of Homeland Security**
- **Department of Veterans Affairs**
- **Department of Defense**
- **Environmental Protection Agency**
- **U.S. Department of Agriculture**
- **Department of Interior**
- **National Science Foundation**
- **Department of Justice**
- **Department of State**
- **Department of Commerce**
- **National Aeronautics and Space Administration**



First NSABB Meeting June 30 and July 1, 2005

- **Criteria** for identifying dual use research and research results
- **Code of Conduct** for life sciences research
- **Communication** of dual use research results
- Strategies for coordination of **international** policies regarding dual use research
- **Synthesis of genomic sequences**



Conclusions

- **Concerns exist about the intentional misuse of research**
- **Risks to public health and security from misuse could be immense**
- **Recombinant DNA Advisory Committee provides a model for the NSABB, as noted by the National Research Council**
- **NSABB will provide cogent recommendations to US government for oversight of dual use research**
- **NSABB will carry out its work in a public and open process**



NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

<http://www.biosecurityboard.gov>